BERGESON & CAMPBELL PC

TSCA: Three Years Later

Milken Institute School of Public Health
Washington, D.C.

June 24, 2019

Oscar Hernandez, Ph.D.
Bergeson & Campbell, P.C.
Washington, D.C.
www.lawbc.com

Overview

- Prioritization
- Risk Evaluation
- Alternative Methods

Prioritization -- Section 6(b)

- Final procedural rule published in July 2017
- Prioritization is the initial step in evaluation of existing chemicals under the Toxic Substances Control Act (TSCA)
- Stated objective:
  - To designate chemicals as either:
    - High-priority for further risk evaluation (RE), or
    - Low-priority where RE is not warranted at the time

Prioritization Process Key Terms

- TSCA requires that the U.S. Environmental Protection Agency (EPA) apply the following standards in designating chemicals as high- versus low-priority:
  - **High-Priority**: "…a [chemical] that [EPA] concludes, without consideration of costs or other nonrisk factors, *may present* an unreasonable risk of injury to health or the environment *because of a potential hazard and a potential route of exposure under the conditions of use*, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by [EPA]"
  - **Low-Priority**: "[EPA] shall designate a [chemical] as a low priority substance if [EPA] concludes, *based on information sufficient to establish*, without consideration of costs or other nonrisk factors, that such substance *does not meet the standard [for a high-priority substance]* "

Prioritization Considerations

- EPA's prioritization process must consider:
  - Hazard and exposure potential
  - Persistence and bioaccumulation
  - Potentially exposed or susceptible subpopulations (PESS)
  - Storage near significant sources of drinking water
  - Conditions of use (COU) or significant changes in COU
  - Volume or significant changes in volume manufactured or processed
  - Other risk-based criteria that EPA determines to be relevant

Status of Prioritization Efforts

- In March 2019, EPA issued a list of 40 chemicals to begin the prioritization process
- Expected outcome is designation of 20 high-priority and 20 low-priority chemicals
- Deadline for completion is **December 2019**

Science Policy Issues and Considerations

- Standards for high- and low-priority designations could push chemicals toward high-priority decisions
- Need for EPA to figure out the role for Section 4 testing in ensuring that:
  - Low-priority decisions can be adequately supported
  - Adequate hazard and exposure data sets exist on high-priorities to inform REs
  - Meeting Section 26 science standards in prioritization while achieving legally supportable low-priority designations

Risk Evaluation

- RE follows prioritization in the TSCA process
- Final procedural rule published in July 2017
- The purpose of RE is to determine whether a chemical under COU presents an unreasonable risk to health or the environment, without consideration of cost or other nonrisk factors, including unreasonable risk to a PESS

Risk Evaluation

- RE process components include:
  - Scope of evaluation
  - Hazard assessment
  - Exposure assessment
  - Risk characterization
  - Risk determination

Status of Risk Evaluation Efforts

- In December 2016, EPA published a list of the "first 10" chemicals for RE

Asbestos	Methylene Chloride
1-Bromopropane	N-Methylpyrrolidone
Carbon Tetrachloride	Perchloroethylene
1,4-Dioxane	Pigment Violet 29
Cyclic Aliphatic Bromide Cluster	Trichloroethylene

- REs on these chemicals must be completed by the **end of 2019** with possible six-month extension

Science Policy Issues and Considerations

- Fit for purpose as a balancing factor
- Meeting Section 26 science standards in completing REs while achieving legally supportable determinations of no unreasonable risk
    - Points arising from Pigment Violet 29 peer review

Section 4(h) Reduction of Testing on Vertebrates

- Section 4(h)(1) calls on EPA to "reduce and replace" the use of vertebrate animals in testing
  - This is to be done to the "extent practicable, scientifically justified, and consistent with" TSCA policies
  - Prior to requiring testing, EPA is to take "reasonably available" information into consideration, including:
    - Toxicity information;
    - Computational toxicology; and
    - Others
  - EPA is also called on to "encourag[e] and facilitat[e]" the use of animal alternative methods and the grouping of chemicals for testing

Strategic Plan

- In June 2018, EPA released its *Strategic Plan to Promote the Development and Implementation of Alternative Test Methods Within the TSCA Program*
- EPA used "new approach methodologies" (NAM) as a broadly descriptive reference to any approach(es) that can provide information on hazard and risk consistent with the statutory mandate
- Strategic Plan has three core components:
  - Identifying, developing, and integrating NAMs for TSCA decisions
  - Building confidence to establish scientific relevance
  - Reliability of NAMs for TSCA decisions

Status of Implementation of Strategic Plan

- Maintain and expand list of NAMs
- Implementing reliable and relevant NAMs for TSCA decisions: fit for purpose
  - Screening candidates for prioritization
  - Prioritization
  - RE
- Interim Skin Sensitization Policy
  - Acceptance of alternative approaches for skin sensitization hazard identification

Science Policy Issues and Considerations

- Achieving acceptance of NAMs in EPA regulatory decisions on new and existing chemicals
- Meeting Section 26 science standards in applying NAMs
- Ensuring that the U.S. and other developed countries can stay reasonably aligned in judgments regarding acceptability of NAM methods and results
  - Achieving "Mutual Acceptance of Data" within the Organization for Economic Cooperation and Development (OECD)

TSCA: Three Years Later

- Developed frameworks, procedures, and tools for implementation of prioritization and RE
  - Outcome of prioritization and RE activities by **end of 2019** will provide basis for objective evaluation
- Approaches and strategies for implementation of NAMs
  - Most developmental activities ongoing or starting in near future
  - Development and integration of NAMs anticipated to be incremental and multiyear process

Thank You

Oscar Hernandez, Ph.D.
Bergeson & Campbell, P.C.
2200 Pennsylvania Avenue, N.W.
Suite 100W
Washington, D.C. 20037
ohernandez@lawbc.com
www.lawbc.com